Intended Use

℞ Only Federal law restricts the sale of the device identified in this manual to, or on the order of, a licensed medical practitioner.

This documentation is intended for use by medical practitioners who perform computer-aided phonocardiography, Holter monitoring, electrocardiography (ECG) and similar tests, and for physicians who interpret heart sounds and ECG data.

AUDICOR's interpretive statements and graphics are designed to enhance the diagnostic process. They are no substitute for the qualified judgment of a properly trained, supervised clinician. As with any diagnostic test, always give consideration to patient symptoms, history and other relevant factors.

AUDICOR testing is indicated for patients who present with cardiac symptoms, including shortness of breath, and for patients who are at risk for heart disease.

AUDICOR testing is indicated only for patients 18 years of age or older. AUDICOR RT analyses are not valid for patients under 18 years of age.

AUDICOR RT Warnings and Cautions

Warning AUDICOR analyses are not valid for patients under 18 years of age.

Warning Before performing defibrillation or applying any high frequency surgical equipment to a patient, remove AUDICOR sensors, AUDICOR adapter connector and ECG electrodes from the chest area. Sensors or electrodes trapped under defibrillator pads or paddles during defibrillation or sensors or electrodes in contact with high frequency electrosurgical equipment can cause patient burns.

Warning The operator should avoid contact and prevent patient contact with pins inside the AUDICOR sensor connector. Contact can result in current leakage in excess of limits permitted by IEC-60601-1.

Warning Use only Ag/AgCL-type ECG electrodes with AUDICOR sensors. Other types of electrodes might result in a leads off condition and incomplete AUDICOR or ECG reports.

Warning Once the AUDICOR sensors or one or more ECG electrodes are connected to a patient, do not allow patient cable connectors or AUDICOR adapter connectors to meet with any grounded or live parts. Contact could cause unacceptable levels of electrical current to flow to the patient.

Warning The quality of ECG and sound signals reported by the AUDICOR RT system may be adversely affected by electromagnetic interference from environmental sources resulting in non-physiological waveforms with the potential for misinterpretation.

Warning Do not use in the presence of flammable gasses.

Warning **Battery may explode or catch fire if mishandled:**

- Do not disassemble or incinerate
- Do not charge except as specified in the instructions
- Do not heat above 60°C (140°F)
- Do not crush
- Do not immerse in water/liquids or cleaning fluids
- Do not abuse or mistreat the battery

See Battery Label: WARNING –"Risk of explosion, do not open or incinerate"

Warning USB Wireless Antenna – This device has not been authorized as required by the rules of the FCC. This device is not, and may not be, offered for sale or lease, or sold or leased, until authorization is obtained.

Warning Audicor *AM* (5-Wire Ambulatory Recording Device) - This device has not been authorized as required by the rules of the FCC. This device is not, and may not be, offered for sale or lease, or sold or leased, until authorization is obtained.

Warning Should a mild or severe skin reaction to the sensor adhesives occur, discontinue use immediately. In this case the patient may experience notable discomfort, pain or burning sensation or a skin rash in and around the sensor area. Clean the affected area of all adhesive residue and apply topical relief as prescribed by the patients physician. For ECG electrodes check manufacturers information for instructions.

Caution Use only your fingers, to touch the Audicor *AM* device buttons. The ink-end of a pen may cause damage.

Caution Simultaneously attaching patient leads for another device could cause the ECG signals to be corrupted.

Caution Attach only AUDICOR adapters to AUDICOR sensors. AUDICOR sensors will not function with other adapters.

Caution Do not allow an AUDICOR sensor to touch an electrode or another sensor. Allowing contact causes recording of incorrect signals.

Caution Do not attach an AUDICOR sensor connector to both an AUDICOR sensor and an ECG electrode at the same time. Should this occur, the ECG signals will be corrupted.

Caution To ensure proper patient isolation and signal quality, securely and properly connect all cables to the AUDICOR Holter device before you attach lead wires to the patient.

Caution Do not allow bleach or other disinfectant to come in contact with the round openings on the underside of the sensor connectors. Doing so will damage the connectors.

Caution Do not allow cables to dangle into the printer area; they can jam the printer at the paper input tray and in the wire paper catcher area.

Caution To avoid damaging AUDICOR components, take the following precautions:

- Do not use organic solvents on any parts of the patient cable or on the AUDICOR *AM*/Holter device.
- Do not immerse AUDICOR AM components in any type of liquid, including water
- Do not perform any type of sterilization procedure on AUDICOR *AM* components

Caution To avoid damaging the Audicor *AM*/Holter device, be extremely careful not to allow fluid into the seams of the *AM* device, especially at any point around the battery door/ compartment. The AUDICOR RT+*AM* warranty does not cover damage from fluids applied to the *AM* device.

Caution There are no serviceable parts in the AUDICOR *AM*/Holter device. Do not open the AUDICOR Holter device except to replace the battery and or the memory/storage card. Doing so voids the warranty.

Caution Be careful to match the battery to the correct charging device before applying AC/Mains power. Look for Inovise Medical and or the Audicor brand as an initial measure of compatibility for both the battery and the charger.

Caution The battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 60°C (140°F), or incinerate. Replace battery with (Inovise Medical, Inc., Part # 20213) only. Use of another battery may present a risk of fire or explosion.

Caution For Holter battery, charging range must be maintained between (0 and +45) degrees C. Maintain discharge within (-10 to +60) degrees C.

Caution Dispose of used batteries properly and according to local standards for Lithium-Ion batteries. Keep away from children. Do not disassemble and do not dispose of in fire.

Caution The Audicor RT+AM System is equipped with wireless telecommunication features. If it appears Audicor RT + AM interfears with the use or operation of other business or medical equipement within the immediate proximity of the device, discontinue use immediately and notify Inovise Medical, Inc. (productsupport@inovise.com)

Adjust Leads, Patient and Environment if Necessary

If you need to improve the signal quality, check these things.

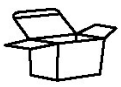
- Ensure good contact between the patient's skin, ECG electrodes and snap adapters, and the AUDICOR sensors and sensor connectors.
- Verify the Audicor AM patient cable is well seated with the AUDICOR *AM*/Holter device.

Tip For optimal results, secure the Audicor Sensors and Holter device with Tegaderm® transparent adhesive pads. This can prevent noise and artifact caused by electrode and sensor movement during recording sessions.

- **3M™ Tegaderm™**, is a registered trademark of the **3M™** Corporation.

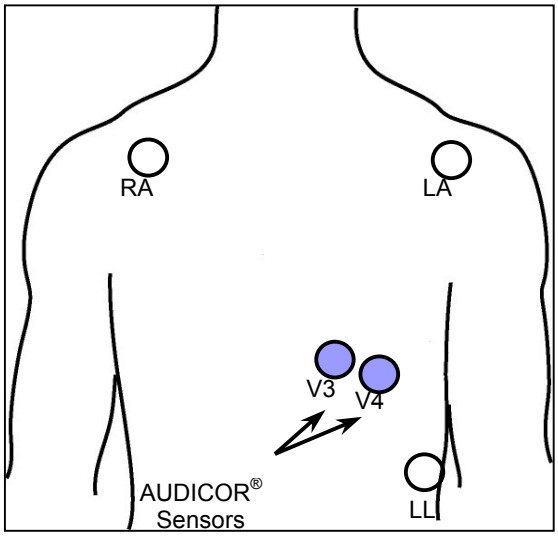
Symbols

The following symbols may appear on the AUDICOR RT, the AUDICOR AM and on the AUDICOR accessories.

REF	Part number/catalog item
SN	Serial number
LOT	Lot number
Rx Only	For use by, or on the order of, a physician
	Date of manufacture (yymmdd)
	Manufacturer
EC REP	Authorized Representative for the CE Mark
	Defibrillator-proof type of CS equipment
	Consult accompanying documents
	Reset
	External Power
	Serial Port
	USB port
	Headphones
	Contains no Latex
	Use by YYYY-MM-DD
	Audicor Sensor
	Sensor Pouch
	Sensor Box

Prepare ECG Electrode and AUDICOR Sensor Sites

Prepare the ECG sites for a 5-lead recording session.



5-Lead Lead Placement Diagram

Place V3 between fourth intercostal space at left sternal border and V4

Place tab electrodes and AUDICOR Sensors in these traditional lead positions.

RA – Right arm at clavicle
LA – Left arm at clavicle
LL – Left leg at hip
V3 – Midway between V2 and V4. Use an AUDICOR sensor here
V4 – Fifth intercostal space left of midclavicular line. Use an AUDICOR sensor here

Inovise Medical, Inc.
8770 SW Nimbus Avenue
Suite D
Portland, Oregon 97008-7196

EC REP

Authorized Representative for the CE Mark Devices:
Priory Analysts
The Atrium, Park Street West
Luton, LU1 3BE, United Kingdom

The Audicor RT + AM System is assembled in the USA

Federal Communications Commission (FCC) Statement

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) this device may not cause harmful interference and

2) this device must accept any interference received, including interference that may cause undesired operation of the device.